DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
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04-BLT-11

February 3, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ralph L. Buckel, DVM, Co-owner
Chestertown Animal Hospital
10530 Augustine Herman Highway
Chestertown, Maryland 21620

Gary R. Hash, DVM, Co-owner
Chestertown Animal Hospital
10530 Augustine Herman Highway
Chestertown, Maryland 21620

Dear Drs. Buckel and Hash,

The Food and Drug Administration (FDA) conducted an inspection at your veterinary clinic located at Chestertown Animal Hospital, 10530 Augustine Herman Highway, Chestertown, Maryland, on August 20 and 27, 2003. The inspection was initiated in response to a United States Department of Agriculture (USDA) report of an illegal gentamicin residue in a bob veal calf offered for sale and slaughter for human food by [redacted] a dairy producer located in Cordova, Maryland ([redacted]). Chestertown Animal Hospital has performed veterinary work for this farm.

Our inspection found that Chestertown Animal Hospital prescribed, compounded, and dispensed gentamicin and combinations of gentamicin with other antibiotics for the treatment of bacterial infections in cows with labeling specifying a 30-day meat withdrawal time. Since gentamicin injection is not approved for use in cows, its extralabel use must comply with FDA's regulations for extralabel drug use in animals, Title 21, Code of Federal Regulation (CFR), Part 530. Among the requirements is that the veterinarian must establish a substantially extended withdrawal period that is supported by appropriate scientific information (21 CFR 530.20(a)(2)(ii)). However, the withdrawal period you have established for the extralabel use of the gentamicin drug products in cows is not supported by appropriate scientific information. According to veterinary literature, no withdrawal period has been scientifically established for gentamicin for use in cattle, and the Food Animal Residue Avoidance Databank (FARAD) advises that a minimum pre-slaughter withdrawal period of eighteen months or more be established.

We note that there have been two recent residue violations involving the use of gentamicin at [redacted] In one, on or about January 24, 2003, the dairy farm sold a bob veal calf for slaughter and USDA analysis identified the presence of 0.65 parts per million (ppm) of gentamicin in liver tissue samples. This residue level is illegal since there is no established tolerance for gentamicin in cattle. Our inspection revealed that you had prescribed and dispensed the combination drug Gentamast

(penicillin/gentamicin) for the treatment of a dam and that this calf received milk from the dam. In the other, [redacted] sold a cow for slaughter on or about June 7, 2002, and USDA analysis identified the presence of 0.61 ppm of gentamicin in kidney tissue. An investigation revealed that Chestertown Animal Hospital dispensed Gentamast for the treatment of that cow.

This letter may not list all the deviations at your facility. As licensed veterinarians, you are responsible for ensuring that all drugs you prescribe and administer comply with all requirements of the Food, Drug, and Cosmetic Act (the Act) and it's implementing regulations.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the investigation and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Ms. Vinetta Howard-King, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215.

Sincerely,

Kirk D. Sooter for

Lee Bowers,
District Director
Baltimore District

Cc: Julie A. Cornett, D.V.M
Branch Chief, Standards and Procedures
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